REMARKS

CLAIM STATUS AND AMENDMENTS

Claims 54-100 were pending in this application when last examined. Claims 1-53 have been canceled. The Office Action indicates that claim 68-94 and 98-100 are withdrawn. Claim 54 is currently amended and new claim 101 has been added. The specification has been amended.

Support for the amendments can be found in the specification, for example, at page 8, lines 11-17. Support for new claim 101 can be found, for example, at page 8, lines 20-23 and 29-30, page 9, lines 13-16, page 12, lines 9-11 and 26-29, and in Figures 5A and 5B. No new matter has been added.

The Office Action indicates that claims 1-53 remain pending. Applicants intended to cancel claims 1-53 in the Preliminary Amendment filed January 18, 2008. Applicants reiterate that claims 1-53 are canceled.

Claims 68-94 and 98-100 include claim status identifiers “Withdrawn”. Applicants have identified these claims as withdrawn without making an admission that these claims are in fact withdrawn. As detailed in the remarks below, the Office Action fails to address the Restriction Requirement of record or make the requirement final and therefore the status of the claims remains unclear.

RESPONSE TO RESTRICTION REQUIREMENT

In the June 12, 2009 Response to Restriction Requirement, Applicants provisionally elected Group I, claims 54-67. Applicants further noted that claims 95-97 were also believed to read on the elected Group.

It appears that the Office has elected the claims of Group I and claims 95-97 for examination on the merits. The Office Action, however, fails to address the restriction or provide any remarks regarding the restriction. The Office Action has also not made the restriction final.

The May 15, 2009, Restriction Requirement contended that the claims of Group I are drawn to an inflatable and expandable gastric tube and that the claims of Group II are drawn to an inflatable and expandable catheter. Applicants again respectfully traverse the restriction.

The Office Action has improperly classified and limited the claims of Groups I and II. Independent claims 54, 68 and 76 are each directed to a device for insertion in a human or animal body or body cavity having an inflatable and expandable means. Furthermore, the additional features recited in each of these claims in no way limits the claims to a gastric tube or to a catheter.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the restriction between the

claims of Group I and Group II, and request the search and examination on the merits of each of claims 54-78.

OBJECTIONS TO SPECIFICATION

At page 2, item 1, the Office Action objects to the specification because of informalities. The amended specification further clarifies the collection bag 16 and the volume of urine 17, shown in Fig. 3. Accordingly, Applicants request reconsideration and withdrawal of the objection.

CLAIM REJECTIONS - 35 USC § 102

RAGHEB et al.

At page 3, item 4, the Office Action rejects claims 54-67 and 95-97 under 35 U.S.C. 102(b) as being anticipated by RAGHEB et al. (US 5,824,049). Applicants respectfully traverse the rejection.

RAGHEB relates to a coated implantable medical device that includes a layer of a bioactive material posited on the surface of the device. In addition, there is also a porous layer (polymer coating) posited over the bioactive layer. The device is designed for use in the vascular system, i.e., a vascular stent, and the typical bioactive material is an antiplatelet or antithrombotic agent such as heparin, or an anti-inflammatory steroid such as dexamethasone. RAGHEB also mentions the use of

antimicrobials or antibiotics from a laundry list of bioactive materials (col. 3, lines 41-51).

In contrast to the presently claimed device, however, RAGHEB fails to teach or suggest a device that includes an inflatable or expandable means containing a solution. The RAGHEB device utilizes a bioactive coating covered with polymer. "A vast range of drugs, medicaments and materials may be employed as the bioactive material in the layer 18, so long as the selected material can survive exposure to the vacuum drawn during vapor deposition or plasma deposition." (*See*, column 8, lines 3-6). "The purpose of the porous layer 20 is to provide a controlled release of the bioactive material when the device 10 is positioned in the vascular system of a patient. The thickness of the porous layer 20 is chosen so as to provide such control." (*See*, column 10, lines 34-38). The solution of the presently claimed device ensures a faster release of the LMAC. Also, because the LMAC is in a solution, it is always possible to provide additional LMAC (i.e., refills) to the device.

Furthermore, RAGHEB fails to teach or suggest a solution or a material comprising at least one component capable of releasing at least one low molecular antimicrobial compound (LMAC) having a molecular weight equal to or less than 250 U. RAGHEB describes a device that includes a layer of bioactive materials that are controllably released through a polymer coating. RAGHEB fails, however, to teach or suggest any component

of a bioactive material having a molecular weight equal to or less than 250 U.

Finally, RAGHEB fails to teach or suggest a solution comprising a component that releases the LMAC upon acidification, as recited in claim 1. As detailed above, the RAGHEB device includes a polymer coating that provides for the controlled release of the bioactive material.

For all of these reasons, RAGHEB fails to teach or suggest, and fails to anticipate the device of claims 54-67 and 95-97. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

BRENNER et al.

At page 4, item 5, the Office Action rejects claims 54, 60 and 61 under 35 U.S.C. § 102(b) as being anticipated by BRENNER et al. (US 5,049,140). Applicants respectfully traverse the rejection.

BRENNER describes a fitting for a medical catheter manufactured from polymer elastomer including an antimicrobial agent. Similar to RAGHEB, the BRENNER device includes an antimicrobial agent embedded in it. The BRENNER device fails to include a solution comprising a component capable of releasing a LMAC having a molecular weight equal to or less than 250 U upon acidification.

Thus, BRENNER fails to teach or suggest, and fails to anticipate the device of claims 54, 60 and 61. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

EPLETT

At page 5, item 6, the Office Action rejects claims 54, 55, 60 and 61 under 35 U.S.C. § 102(b) as being anticipated by EPLETT (US 5,505,695). Applicants respectfully traverse the rejection.

EPLETT describes a urethral catheter with an antiseptic cuff comprising a resilient biocompatible sponge charged with antimicrobial substance. Again, like RAGHEB and BRENNER, fails to teach or suggest that the antimicrobial substance is a LMAC having a molecular weight equal to or less than 250 U, as featured in the device of present claim 1. EPLETT also fails to teach or suggest that the LMAC is released upon acidification.

Thus, BRENNER fails to teach or suggest, and fails to anticipate the device of claims 54, 55, 60 and 61. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

NEW CLAIM 101

New claim 101 is directed to a medical device for insertion into a human or animal body or body cavity and recites

structural features that distinguish the device over the teachings of RAGHEB, BRENNER and/or EPLETT. In particular, the device of claim 101 features an inflatable and expandable cuff surrounding one end of the device, and at least one component retained within the cuff capable of releasing at least one low molecular antimicrobial compound (LMAC) upon acidification, wherein the LMAC has a molecular weight equal to or less than 250 U and is capable of permeating the cuff to the adjacent tissue or body cavity and exerting an antimicrobial effect.

POWER OF ATTORNEY

Applicants submit herewith an executed Revocation and Power of Attorney in regard to this application.

CONCLUSION

Entry of the above amendments is earnestly solicited. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The fee of $136.00 for the extra independent claim added and additional claim of any type is being paid online simultaneously herewith by credit card.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/H. James Voeller/

H. James Voeller, Reg. No. 48,015
Customer No. 00466
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

HJV/jr

APPENDIX:

The Appendix includes the following item:

☒ - an executed Revocation and Power of Attorney